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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,597	06/12/2008	Janet Shipley		9071

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EXAMINER

FETTEROLF, BRANDON J

ART UNIT	PAPER NUMBER
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1642

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,597	Applicant(s) SHIPLEY ET AL.	
	Examiner BRANDON J. FETTEROLF	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-19, as specifically drawn to the special technical feature of a method of inhibiting the proliferation of a target cell, comprising contacting the cell with a GPC5 antagonist of a GPC5 binding agent.

Group 2, claim(s) 20-29 and 34-41, as specifically drawn to the special technical feature of a method of determining the susceptibility of a cancer to treatment with a GPC5 antagonist or binding agent, comprising determining the presence, absence or level of expression of GPC5 and/or WT1 in a cell from said cancer.

Group 3, claim(s) 30-33, as specifically drawn to the special technical feature of a method of screening for an agent capable of inhibiting proliferation of a target cell..

The inventions listed as Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

In the instant case, the single general inventive concept under PCT Rule 13.1 which combines Groups 1-3 appears to be the nexus between GPC5 expression and cancer.

However, Yu et al. (J. Hum. Genet. 2003; 48: 331-335) teach that GPC5 is overexpressed in lymphoma cell lines and over-expression of GPC-5 contributes to the development and/or progression of lymphomas and other tumors (Abstract).

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Therefore, the technical feature linking the inventions of Groups 1-3 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

This application contains claims directed to more than one patentably distinct inventions, NOT species. These inventions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The patentably distinct inventions are:

- a) an antibody as the GPC5 antagonist/binding agent;
- b) a peptide as the GPC5 antagonist/binding agent;
- c) an antisense RNA as the GPC5 antagonist;
- d) a dsRNA such as RNAi or siRNA as the GPC5 antagonist; and
- e) a ribozyme as the GPC5 antagonist.

Each of the specifically claimed GPC5 antagonist and/or binding agents do not share substantial structural similarities although they have a common utility, i.e. antagonize or bind to GPC5. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300(CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). As such, these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required, in reply to this action, to elect a single invention to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

If claims are added after the election, applicant must indicate which are readable upon the elected invention. MPEP § 809.02(a).

The claims are deemed to correspond to the invention listed above in the following manner:

From Group 1, Claims 8 and 17 correspond to groups a and b, and claims 14-15 correspond to groups c-e from above.

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Additionally, this application contains claims directed to more than one patentably distinct inventions, NOT species. These inventions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The patentably distinct inventions are:

- a) GCP5; and
- b) WT1.

Each of the specifically claimed genes do not share substantial structural similarities although they have a common utility, i.e. determining susceptibility to a cancer. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300(CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). As such, these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required, in reply to this action, to elect a single invention to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

If claims are added after the election, applicant must indicate which are readable upon the elected invention. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Group 2, Claims 20-28 correspond to groups a and b.

Species Election

This application contains claims directed to more than one species. These inventions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a) rhabdomyosarcoma;
- b) lymphoma;
- c) non-small cell lung cancer;

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- d) bladder cancer;
- e) breast cancer;
- f) prostate cancer;
- g) a neuroglial tumour;
- h) squamous cell carcinoma of the head and neck;
- i) leukemia;
- j) leiomyosarcoma;
- k) liposarcoma;
- l) malignant fibrous histocytoma of bone or soft tissues;
- m) melanoma;
- n) mesothelioma;
- o) thyroid cancer;
- p) lung cancer;
- q) testicular cancer; and
- r) ovarian cancer

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

If claims are added after the election, applicant must indicate which are readable upon the elected invention. MPEP § 809.02(a).

The claims are deemed to correspond to the invention listed above in the following manner:

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From Group 1, Claim 5, Group 2 claim 24 and Group 3 claim 33.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Brandon J Fetterolf
Examiner
Art Unit 1642

/Brandon J Fetterolf/
Examiner, Art Unit 1642